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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,978

06/15/2006

Morten Bryhn

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EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

03/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,978	Applicant(s) BRYHN ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-22,37-46 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-22,37-46 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1 sheet, 6/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Remarks filed on 15 December 2008 have been acknowledged and duly made of record.

Response to Arguments

The Rejection under 35 U.S.C. § 112, Second Paragraph has been averred by applicants due to the amendment in the Preliminary Amendment filed on 15 June 2006. Accordingly, the amendment of claims 15 and 41 are acknowledged and the Rejection Under 35 U.S.C. § 112, Second Paragraph is hereby withdrawn.

The Rejection under 35 U.S.C. § 112, First Paragraph has been averred by applicants due to the alleged oversight by Examiner in incorrectly assessing the full content of disclosure directed to prevention in the specification. The Examiner concedes on the error in view of such disclosure. Accordingly, the definition as disclosed cites on page 21, lines 12-15 of specification:

As used herein, the term prevention of body weight gain also means inhibiting body weight gain and effecting or controlling weight loss.

Applicants' arguments have been considered and the Rejection under 35 U.S.C. § 112, First Paragraph is hereby withdrawn.

The Rejection under 35 U.S.C. § 102(b) has been averred by applicants due to the Breivik et al. allegedly failing to teach each and every element of the claim being rejected.

Applicants' arguments are considered but are not found persuasive.

Breivik et al. is maintained because of the limitation in the instant claim directed to '*or any combinations thereof*'.

Breivik et al. adequately addresses the limitations of claim 14 by teaching the limitation where X is 1.

Breivik et al. adequately addresses the limitations of claim 15 by teaching a ratio ranging from 1:1 and 1:2, EPA: DHA.

Applicants' disclose in the latest Remarks that DHA is preferred as the greater concentration but the instant claims disclose embodiments where DHA in the greater concentration is not necessarily claimed as the invention via the ranges in 15 and 41.

Further, applicants aver that Breivik et al. does not support or suggest the risk factors in the instant claim set.

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However, Brievik et al. clearly teaches a method for the treatment or prophylaxis of hypertriglyceridemia with a formulation of EPA: DHA in a ratio ranging from 1:2, which adequately supports and suggest the limitation of claims 15 and 41. The one of skill would be inclined to anticipate that if a condition such as hypertriglyceridemia is treated which is associated with metabolic disorders such as an obesity disorder, that this same ratio or a derivative thereof in the scope of the claimed invention would reasonably anticipate the treatment for an overweight condition.

The Rejection under 35 U.S.C. § 103(a) is averred by applicants for the same reasons directed to Breivik above and further in view of Corkey et al.

In consideration of applicants' disclosure with regard to the Corkey et al. reference, the said reference is withdrawn.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 13-22, 37-46, and 49-52 are pending in this application. Claims 1-12, 23-36, 47, and 48 were canceled in the Preliminary Amendment filed on June 15, 2006. Applicant amends claims 13-22, 37-46, 50, and 51 for clarification and to correct grammatical errors. Claims 39 and 51 are further amended to correct antecedence. Support for new claim 52 may be found throughout the specification, for example pages 1, 6-7, and 15. No new matter is added by any of the amendments herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-22, 37-39, 42- 45, and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Breivik et al. (USPN 5,502,077).

Breivik et al. teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids. The compositions can be used for the [...] *prophylaxis* of multiple risk factors for cardiovascular diseases (abstract only).

Breivik et al. teach that present invention relates to a fatty acid composition comprising at least 80% by weight of omega-3 polyunsaturated fatty acids, wherein at least 75% by weight of the total fatty acids comprise omega-3 (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) C 20:5 and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid (DHA) C 22:6 9column 1, lines 5-10).

Breivik et al. teach the same and exact preferred ratio limitation in the instant claims. The upgrading of the EPA fraction to obtain a weight ratio of EPA: DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain an EPA: DHA weight ratio of from 1:1 to 1:2 may be achieved in the molecular distillation stage. The method also provides the possibility of using supercritical fluid extraction and/or chromatography in the second stage with CO.sub.2 eventually containing a more polar modifier, such as ethanol, in order to concentrate the EPA and/or DHA fraction (column 3, lines 61-67; column 4, lines 1 and 2).

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Breivik et al. teach fish oil which is of animal origin (column 1, line 38). This limitation of oil also anticipates the limitation in the claims drawn to a liquid form (claim 51).

Additionally, it is well-known in the art of pharmacy technology that consumable oil formulations may be extrapolated into emulsion formulations which are essentially oil in water formulations indicated for oral administration

Breivik further anticipates the claimed invention by teaching that this preferred ratio of EPA: DHA has an advantageous effect on risk factors for cardiovascular diseases (column 2, lines 50-67).

Breivik et al. teaches an esterified formulation comprising EPA: DHA (column 3, lines 24-39).

Thus Breivik et al. fully anticipates each and every element of the claimed invention drawn to the limitation of *prevention which encompasses prophylactic treatment* within instant claim 1 and all claims dependent from claim 1.

The subject matter is identical and interchangeable. The inventive objective of the claimed invention is specifically drawn to specific embodiments drawn to ratios of EPA: DHA. Accordingly, the inventive objective is adequately met and encompassed by the methods, teachings, modifications, and inherencies within the Breivik et al. reference. Additionally, the limitations of the instant claims drawn to preventing body weight gain, treatment for obesity, or an overweight condition are well-known in the pertinent art and to one of skill as risk factors for cardiovascular disease as disclosed in the Breivik et al. reference. Further as evidence and incorporated by reference, Breivik et al. (USPN 5945318) lends support to the propensity of a marine oil being incorporated into foodstuffs (which generically encompasses foodstuffs). As is

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well known, EPA and DHA are proving increasingly valuable in the pharmaceutical and food supplement industries in particular. These acids are found in relatively high concentrations in certain marine oils, but for many purposes it is necessary that the marine oils should be refined in order to increase the content of EPA and/or DHA to suitable levels, or to reduce the concentrations of, or even eliminate, certain other substances which occur naturally in the raw oil. For pharmaceutical and food purposes, for instance, it is necessary to substantially completely eliminate all the pesticide residues which commonly occur in marine oils, even those derived from fish caught in sea areas quite remote from intensively cultivated land areas (abstract only). This reference by way of evidence supports the 'snack' limitation. Snacks are edible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-22, 41, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (USPN 5,502,077) in view of Corkey et al.

Breivik et al. teach a fatty acid composition comprising at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid comprises at least 75% by weight of the total fatty acids. The compositions can be used for the *treatment* [...] of multiple risk factors for cardiovascular diseases (abstract only).

Breivik et al. teach that present invention relates to a fatty acid composition comprising at least 80% by weight of omega-3 polyunsaturated fatty acids, wherein at least 75% by weight of the total fatty acids comprise omega-3 (all-Z)-5,8,11,14,17-eicosapentaenoic acid (EPA) C 20:5 and (all-Z)-4,7,10,13,16,19-docosahexaenoic acid (DHA) C 22:6 9column 1, lines 5-10).

Breivik et al. teach the same and exact preferred ratio limitation in the instant claims. The upgrading of the EPA fraction to obtain a weight ratio of EPA: DHA of from 1:1 to 2:1, especially 3:2 or the upgrading of the DHA fraction to obtain an EPA: DHA weight ratio of from

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1:1 to 1:2 may be achieved in the molecular distillation stage. The method also provides the possibility of using supercritical fluid extraction and/or chromatography in the second stage with CO.sub.2 eventually containing a more polar modifier, such as ethanol, in order to concentrate the EPA and/or DHA fraction (column 3, lines 61-67; column 4, lines 1 and 2).

Breivik et al. teach fish oil which is of animal origin (column 1, line 38). This limitation of oil also anticipates the limitation in the claims drawn to a liquid form (claim 51).

Breivik further anticipates the claimed invention by teaching that this preferred ratio of EPA: DHA has an advantageous effect on risk factors for cardiovascular diseases (column 2, lines 50-67).

Breivik et al. teaches an esterified formulation comprising EPA: DHA (column 3, lines 2-39).

Breivik et al. does not go into specific detail as to risks of cardiovascular disease in view of the specific treatment thereof.

However, Corkey et al. essentially teach dietary products for infant child and adult nutrition which possess adequate levels and **ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids**. Consumption of these dietary products can contribute to the prevention of obesity in developing individuals and can contribute to a **reduction in body fat mass in individuals who are trying to loose weight or reduce body fat mass (e.g., obese individuals)**. A first preferred product is a dairy supplement or formulated dairy product for consumption by infants or children to prevent development of obesity. A second preferred product is a **dietary supplement** for persons combating unwanted weight gain or obesity. Also featured are methods of formulating these dietary products (abstract only).

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Corkey et al. teach a combination of MCFA and DHA Reduces Lipogenesis, Lipid Storage, and Secretion from Liver Cells (Please see example 12, paragraphs 121 and 122).

Corkey et al. teach dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006].

Corkey et al. teach [...].Because the .omega.-3 long chain fatty acids (EPA:DHA) have been shown to efficiently inhibit fatty acid synthesis, it is proposed that mixing MCFA with a small portion of EPA and DHA will synergize the positive effects of both types of fatty acids in reducing fat storage in adipose tissue and fat product [0121].

Corkey et al. teach a dietary regimen to be incorporated concomitantly with the said weight-reduction formulation. The present invention features dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets) [0006]; [0034].

Corkey et al. teach a triglyceride form of the formulation. A glyceride is an ester of glycerol (1, 2, 3-propanetriol) with acyl radicals of fatty acids and is also known as an acylglycerol. If only one position of the glycerol molecule is esterified with a fatty acid, a "monoglyceride" is produced; if two positions are esterified, a "diglyceride" is produced; and if all three positions of the glycerol are esterified with fatty acid a "triglyceride" or "triacylglycerol" is produced. A glyceride is called "simple" if all esterified positions contain the same fatty acid; or "mixed" if different fatty acids are involved. The carbons of the glycerol backbone are designated sn-1, sn-2 and sn-3, with sn-2 being in the middle and sn-1 and sn-3 being the ends of the glycerol [0033].

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Thus, it would be *prima facie* obvious to one of ordinary skill in the art to at once recognize a reasonable expectation of success via the incorporating together the methods and teachings of Breivik et al and Corkey et al. Determining the scope and contents of the prior art in view of the immediate references *supra* has been reasonably assessed.

Consummately, the Breivik et al. reference teaches the current invention. The specificities drawn to a particular target population suffering from specific risks and disorders associated with cardiovascular diseases in need of such formulations are adequately supported and taught by Corkey et al.

Accordingly, the level of ordinary skill in the pertinent art suggests well-known and well-established protocols which are sufficiently described, defined, and explained in the references above. As a result, the inventive objective of current invention is made obvious. In consideration of the objective evidence present in the current application, it would have been *prima facie* obvious to combine the references together in obviousness over the claimed invention.

In view of the differences, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to employ the fatty acid composition for treating persons with obesity because it is well-established in the art that the administration of such supplements aid in the treatment of weight control. Based on the secondary reference, Corkey et al. teach ratios of medium chain fatty acids and .omega.-polyunsaturated fatty acids. Further, the said reference teaches consumption of these dietary products [which] can contribute to the prevention of obesity in developing individuals and can contribute to a reduction in body fat mass in individuals who are trying to loose weight or reduce body fat mass (e.g., obese

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individuals). Accordingly, the reference of Corkey et al. reads on dietary formulations of the said fatty acids.

Similarly, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a dietary composition either in the form of a snack or emulsion. Accordingly, the reference of Corkey et al. reads on dietary formulations of which the said fatty acids are comprised.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1617
TEB